

Effect of Long-Acting Cabotegravir on Weight When Used as Pre-Exposure Prophylaxis

Summary

- In HPTN 077, a median increase of ~1 kg in weight was reported in participants receiving long-acting cabotegravir (CAB LA) through Week 41.
- In HPTN 083, a median increase of 1.23 kg/year was reported in participants receiving CAB LA.
- In HPTN 084, an increase of 2.4 kg/year was reported in participants receiving CAB LA.
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HPTN 077

Change in weight was assessed among HIV-uninfected participants enrolled in HPTN 077, a Phase 2a clinical trial that evaluated the safety and pharmacokinetics of CAB LA for pre-exposure prophylaxis (PrEP).¹

Table 1. Median (Q1, Q3) Change From Baseline in Weight (kg) through Week 41¹

	CAB LA (N = 134)	Placebo (N = 43)	P value for difference
Week 41	+1.1 (-0.9, 3) (n = 108)	+1 (-2, 3.2) (n = 38)	<i>P</i> = 0.66

CAB LA = long-acting cabotegravir

A ≥ 5% increase in weight from baseline to Week 41 was seen in 24 (22%) CAB LA participants and in 7 (18%) placebo participants (*P* = 0.62).¹

HPTN 083

Change in weight was assessed post-hoc among HIV-uninfected individuals enrolled in HPTN 083, a Phase 2b/3 clinical trial that evaluated the efficacy and safety of CAB LA for PrEP in cisgender men and transgender women who have sex with men.²

Table 2. Median Change from Baseline in Weight in HPTN 083²

	CAB LA kg/year (95% CI)	TDF/FTC kg/year (95% CI)
Overall	1.23 (1.05, 1.42)	0.37 (0.18, 0.55)
Weeks 0 – 40	1.26 (0.98, 1.54)	-0.50 (-0.78, -0.22)
Weeks 40 – 105	1.11 (0.82, 1.41)	1.19 (0.90, 1.49)

CAB LA = long-acting cabotegravir; TDF/FTC = tenofovir disoproxil fumarate/emtricitabine; kg = kilograms; CI = confidence interval

HPTN 084

Change in weight was assessed among HIV-uninfected individuals enrolled in HPTN 084, a Phase 2b/3 clinical trial that evaluated the efficacy and safety of CAB LA for PrEP in cisgender women.³

In the CAB LA arm there was a small increase in the average initial weight gain relative to the TDF/FTC arm (0.4 kg [95% CI 0.27, 0.51]; $P < 0.0001$).³

Table 3. Change from Baseline in Weight in HPTN 084³

	CAB LA kg/year (95% CI)	TDF/FTC kg/year (95% CI)
Overall	2.4 (1.9, 3.0)	2.1 (1.9, 2.4)

$P = 0.041$

CAB LA = long-acting cabotegravir; TDF/FTC = tenofovir disoproxil fumarate/emtricitabine; kg = kilograms; CI = confidence interval

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In order for ViiV Healthcare to monitor the safety of our products, we encourage healthcare professionals to report adverse events or suspected overdoses to the company at 877-844-8872. Please consult the attached Prescribing Information.

This response was developed according to the principles of evidence-based medicine and, therefore, references may not be all-inclusive.

REFERENCES

1. Landovitz RJ, Zangeneh SZ, Chau G, et al. Cabotegravir Is Not Associated With Weight Gain in Human Immunodeficiency Virus-uninfected Individuals in HPTN 077. *Clin Infect Dis.* 2020;70(2):319-322. doi:<http://dx.doi.org/10.1093/cid/ciz439>.
2. Landovitz R DD, Clement ME, et al. Cabotegravir for HIV prevention in cisgender men and transgender women. *NEJM.* 2021;385(7):595-609. doi:<http://dx.doi.org/10.1056/NEJMoa2101016>.
3. Delany-Moretlwe S, Hughes JP, Bock P, et al. Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomised clinical trial. *Lancet.* 2022;399(10337):1779-1789. doi:[http://dx.doi.org/10.1016/S0140-6736\(22\)00538-4](http://dx.doi.org/10.1016/S0140-6736(22)00538-4).